UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY PATENT LITIGATION	No. 04-MDL-1592 Judge Mark L. Wolf

ABBOTT BIORESEARCH CENTER'S OPPOSITION TO COLUMBIA UNIVERSITY'S EMERGENCY MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Fearing a decision on the merits invalidating its '275 patent and potentially influencing the PTO's evaluation of still-pending claims, Columbia now wants this case to go away. But Columbia does not want to give up all of the rights it must in order to make that happen. Instead, Columbia wants to leave the specter of patent infringement claims -- including claims for some current activities -- hanging over the plaintiffs' heads. Columbia also refuses to provide any covenant at all for plaintiffs' affiliates that could be sued, even today, for infringement in their own right. Columbia cannot have its cake and eat it too -- it must provide a complete covenant or be prepared to defend the validity and enforceability of its patent now.

Columbia is wrong when it suggests that all it needs to do is parrot the covenant discussed in the Federal Circuit's *Super Sack* opinion to divest the plaintiffs of jurisdiction in this case. Indeed, neither *Super Sack*, nor any other prior Federal Circuit decision discussing covenants not to sue, have addressed the complex issues that are uniquely presented by the biotechnology patent claims and products at issue here. Pharmaceutical products, by their

nature, require extensive research and development spanning years of work, and thus so-called "pipeline products" are of special interest and concern regarding the scope of the covenant. Moreover, Columbia's '275 patent has claims drawn specifically to intermediary-type (*i.e.* non-commercial) products, and thus it is possible to infringe the patent prior to commercial sale of a product. Columbia's original covenant provided no coverage for pipeline products, and its recent "clarification" of the covenant still leaves open loopholes that could subject the plaintiffs to liability for current activities.

Moreover, while Abbott Bioresearch Center, Inc. ("ABC") is technically the named plaintiff in this action, numerous other Abbott entities are subject to possible infringement allegations under the '275 patent. For example, Abbott Laboratories, Inc. markets the primary product-at-issue -- HUMIRA®, a monoclonal antibody treatment for rheumatoid arthritis and potentially other diseases. In addition, Abbott Biotechnology, Limited ("ABL") also currently sells HUMIRA®, and there are plans to have ABL manufacture the product in the future. These entities, and any other successors-in-interest to the HUMIRA® asset, must be provided the same covenant that ABC will be provided. Anything less leaves ABC with an asset encumbered by potential claims by Columbia against current and planned activities, and does not fully remove the cloud of infringement that ABC sought to remove through this case.

Only a covenant tailored to the unique facts of this case, and specifically to ABC's unique circumstances, can properly divest this Court of jurisdiction over ABC's complaint. Columbia is apparently unwilling to provide such a covenant. ABC does not want to perpetuate this litigation unnecessarily, but Columbia's covenant in its current form is simply insufficient. Accordingly, ABC respectfully requests the Court to deny Columbia's motion to dismiss.

I. THE FACTS -- COLUMBIA'S COVENANT NOT TO SUE AND RECENT "CLARIFICATIONS"

The facts leading up to this motion have evolved over the last several weeks. Columbia first notified plaintiffs of its intention to provide a covenant not to sue on September 1, 2004 (the "Covenant", Ex. A[1]), and moved to dismiss this action one day later. In a telephonic hearing the following week, the Court encouraged Columbia to clarify the scope of its Covenant and the status of plaintiffs' licenses. 9/9/04 Hearing Tr. at 35.

Columbia sent a letter to all plaintiffs on September 10, 2004 purporting to clarify the scope of the Covenant Ex. B. Columbia clarified that the Covenant applied to "any claim of any reissued or reexamined version of the '275 patent that is the same as, or substantially identical to, a claim of the '275 patent as it currently reads."[2] *Id.* Columbia also clarified that the Covenant "applies to any product currently made, used, offered for sale, sold, or imported by plaintiffs, or any product that was made, used, offered for sale, sold, or imported by plaintiffs prior to the date of the Covenant." *Id.* On the other hand, Columbia also stated that the Covenant ***did not*** cover (1) a plaintiff's affiliates or customers, or (2) any claim in any patent that may issue in the future based upon the pending '159 application, irrespective of whether that claim is the same as, or substantially identical to, a claim of the '275 patent as it currently reads. *Id.*

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[1] All references to exhibits herein are attached to the Affidavit of Michael S. D'Orsi In Support Of Abbott Bioresearch Center's Opposition To Columbia University's Emergency Motion to Dismiss For Lack Of Subject Matter Jurisdiction, filed herewith.

[2] When reading the Covenant in conjunction with 35 U.S.C. § 252 governing reissue practice, therefore, Columbia has no ability to seek damages for any activities occurring prior to the reissuance of the '275 patent.

In a separate letter sent to ABC's counsel on September 13, 2004, Columbia informed ABC that it was withdrawing the notice of termination dated March 9, 2004. Ex. C. Columbia confirmed the effect of this withdrawal was that ABC's License Agreement was "in full force and effect retroactive to the date on which the termination otherwise would be effective." *Id.* Despite this withdrawal, Columbia expressly confirmed it was "not waiving any grounds for termination of the License Agreement, except for failure to pay royalties based on the '275 patent as it currently reads with respect to any product currently made, used, offered for sale, sold, or imported by Abbott, or any product that was made, used, offered for sale, sold, or imported by Abbott prior to the date of the Covenant Not to Sue." *Id.*

Seeking further clarity regarding the scope of Columbia's Covenant, a letter was sent on September 15, 2004 on behalf of all plaintiffs posing additional questions regarding the Covenant. Ex. D. Columbia's counsel responded to these questions in a letter dated September 17, 2004. Ex. E. While the extent of Columbia's most-recent clarifications can be viewed in Exhibit E, they generally involved Columbia's agreement that most (but not all) pre-commercial activities prior to September 1, 2004 with respect to products "in the pipeline" would be covered by the Covenant. On the other hand, Columbia reiterated that the Covenant ***did not*** cover any new development activity performed after the date of the Covenant -- September 1, 2004. Moreover, Columbia stated that "[t]he Covenant does not extend to any claim in any patent that may issue in the future based on the '159 application, without exception." *Id.* Finally, Columbia provided no additional coverage with respect to plaintiff affiliates or assignees regarding products otherwise covered by the Covenant. *Id.*

On September 20, Columbia sent a letter to counsel for ABC, Biogen, Genzyme and Johnson & Johnson putting the parties on notice that it intended to argue in its reply brief on

this motion that the Federal Circuit's decision in *Gen-Probe v. Vysis*, 359 F.3d 1376 (Fed. Cir. 2004), further supported dismissal of this action. Ex. F. Having received notice of this new argument less than 48 hours before this opposition brief was due, counsel for ABC, Biogen and Genzyme sought agreement from Columbia for a modest 1-2 day extension of the briefing schedule. Columbia's counsel refused this request.

In addition to these written communications, counsel for ABC has also had telephone conservations with counsel for Columbia in an attempt to gain further clarity about the scope of the covenant, and to assess the prospects for settlement. While ABC believes it has made reasonable demands regarding the scope of the covenant -- as detailed in its arguments below -- Columbia has been unwilling to accede to these demands, thus necessitating the filing of this opposition brief.

II. COLUMBIA'S COVENANT LEAVES PLAINTIFFS WITH A LICENSE ENCUMBERED BY THE THREAT OF INFRINGEMENT LAWSUITS AGAINST AFFILIATES OR ASSIGNEES.

Columbia's Covenant is initially insufficient because it does not provide any release with respect to entities that could be sued for the same actions -- *e.g.*, making the same product, even under the same tradename -- that are addressed in the Covenant to Plaintiff ABC. Plaintiff ABC is the current manufacturer of HUMIRA®, and thus is a proper declaratory judgment plaintiff. But there are other Abbott affiliates that market and sell the product that could be proper declaratory judgment plaintiffs and that would be covered by an appropriate covenant. Moreover, the covenant should be transferable along with the rights to make and sell HUMIRA®, and thus the covenant should be extended to assignees as well. By not agreeing to a covenant of this scope, Columbia's motion to dismiss must be denied.

A. Columbia's Covenant does not divest the court of jurisdiction as it wants to retain claims relating to affiliates of Plaintiff ABC.

ABC has made the reasonable demand to Columbia that affiliates of Plaintiff ABC should be covered by Columbia's Covenant. Columbia has refused.

ABC is the successor-in-interest to the License Agreement with Columbia, currently makes and sells the allegedly-covered product (HUMIRA®), and thus was chosen as the most logical plaintiff to bring this action. But many other entities under the Abbott umbrella of companies, including but not limited to Abbott Laboratories and Abbott Biotechnology, Limited, also market and sell HUMIRA®, and thus have the same reasonable apprehension of a Columbia lawsuit that ABC did when initially bringing this case. Having such reasonable apprehension, they could be proper plaintiffs in this (or a similar) action, and Columbia should thus extend the Covenant to cover them.

The Covenant should also be extended more broadly to cover all Abbott affiliates, commensurate with the scope of the original License Agreement with Columbia.[3] Abbott has concrete plans to shift HUMIRA® manufacturing to another Abbott entity, Abbott Biotechnology, Limited, in the near future, and ABL has began construction of a plant in Puerto Rico. Declaration of Jochen Salfeld (Ex. I), at ¶ 5. This alone is enough to support jurisdiction. *See, e.g. Genentech, Inc. v. Eli Lilly and Co.*, 998 F.2d 931, 936 (Fed. Cir. 1993) ("preparing to act" in a manner the patentee will assert as infringing is enough to support jurisdiction). Moreover, there are other Abbott affiliates which may be involved in cross-marketing or selling HUMIRA® now and in the future. *Id.* at 6-7. These affiliates rightfully fear possible infringement claims relating to these activities. As such, ABC's License Agreement with

[3] ABC's License Agreement with Columbia grants to "Licensee and its Affiliates," with "Affiliates" defined to include "any corporation or other business entity that directly or indirectly controls, is controlled by, or is under common control with, Licensee." Ex. G at ¶¶ 1(a) and 2(a).

Columbia is drawn to extend to cover ABC's affiliates. Ex. G. But Columbia's Covenant does not extend to cover ABC's affiliates.

The practical impact of Columbia's position is that Abbott would be forced to add its affiliates as plaintiffs in this case, or to bring a new lawsuit, for those entities that presently make, use, offer to sell, or sell any products under the '275 patent. And Abbott will also be forced to bring a new lawsuit every time a new Abbott entity engages in arguably infringing activities relating to HUMIRA®. While Columbia might provide a new covenant to each entity that would come forward, it simply makes no sense to have this merry-go-round of lawsuits and covenants. Columbia should be forced to defend these '275 patent claims now.

B. **Columbia's covenant does not divest the court of jurisdiction because the covenant is not assignable with the products-at-issue.**

Another failure of Columbia's covenant is that it is not assignable with the products-at-issue. Columbia has provided a Covenant that covers, at least as to ABC, the HUMIRA® product. But if ABC is to transfer the HUMIRA® asset to another corporate entity, even within the Abbott corporate family, the Covenant (according to Columbia) would not transfer with the HUMIRA® asset. This would leave the assignee of HUMIRA® subject to patent infringement claims for activities occurring prior to any reissuance of the '275 patent (*i.e.* even for claims that are the same or substantially identical). With this kind of encumbrance on the HUMIRA® asset, it effectively leaves Abbott with an asset that cannot be easily sold or transferred, thus diminishing the overall value of the asset in Abbott's hands.

The only reasonable solution to this problem is that the Covenant must be assignable with the products (or pipeline products) that Columbia has agreed it covers. HUMIRA® should be covered to the extent outlined in the Covenant, whether it is made, used or sold by ABC or any other entity. Indeed, the Federal Circuit case law on the issue of covenants

has emphasized that it is ***the current products*** that are covered by a covenant not to sue. *See, e.g. Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059 (Fed. Cir. 1995) (emphasizing focus on absolute covenant regarding "past and present products"); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 638 (Fed. Cir. 1991) (patentee estopped through covenant from "asserting liability for the making, selling or using of ***any Spectronics product*** that would infringe the claims of the '366 patent" (emphasis added)). Columbia has refused to provide a complete, transferable covenant that is tied to ABC's "past and present products," including HUMIRA®. Thus, Columbia's Covenant falls short of what is required by the case law to divest this Court of jurisdiction.

III. COLUMBIA'S COVENANT FAILS TO RELEASE CLAIMS AS AGAINST ALL PRODUCTS CURRENTLY IN ABBOTT'S PIPELINE, AND THUS IS INSUFFICIENT.

Columbia's September 1, 2004 Covenant does not address the issue of products that are not yet sold by plaintiffs, but rather are "in the pipeline" to be produced and sold commercially in the future. In response to an inquiry from plaintiffs, Columbia did provide some clarification that its Covenant should be construed to cover certain pipeline products, and specifically those that have been generated as of the date of Columbia's covenant. But even in light of Columbia's clarification, there remain other pipeline products and research activities that, while presently subject to an infringement lawsuit from Columbia, are not covered by Columbia's Covenant.

ABC is presently involved in significant research into various possible antibodies to certain target antigens. Salfeld Decl. at ¶ 9. There are transformed cells and DNA constructs

that encode various proteins that are being investigated as possible treatments for such indications as Crohn's Disease and Multiple Sclerosis. *Id.* at ¶ 9.[4] While ABC has taken concrete steps to develop these new products, Columbia's clarifications to its Covenant suggest that any modifications to a transformed cell or DNA construct after September 1, 2004 would cause any resulting products to fall outside the scope of the Covenant. Thus, for example, a DNA construct created for the first time last week would not be exempted from infringement liability by Columbia's current Covenant.

It is also important to note that the claims of the '275 patent -- covering such intermediary concepts as DNA constructs and transformed cells -- would cover the products of research work before such work necessarily leads to commercially-sold products. Given the nature of the Axel patent claims, it is thus especially imperative to provide a covenant exempting all of these pre-commercial activities with respect to products that are in the pipeline.

Abbott generally, like any biotech or pharmaceutical company, has ongoing research into various new products that are at all stages on the continuum of development. New or revised constructs, transformed cells, and proteins are generated nearly every day. Salfeld Decl. at ¶ 8. Columbia has provided plaintiffs with a confusing and contradictory set of "clarifications" regarding these pipeline activities that makes only one thing certain -- there are activities currently being engaged in by ABC and its affiliates that (1) Columbia wants to be able

[4] ABC has at least three drug candidates -- referred to as ABT-874, ABT-325, and ABT-007 -- in various stages of pre-clinical or clinical trials that would allegedly be covered by the '275 patent claims. Salfeld Decl. at ¶ 11. Based on Columbia's clarifications of its Covenant in its September 17 letter, there is apparently no remaining dispute that ABC's activities as to these "pipeline products" are covered by the Covenant.

to allege practice a claim of the original '275 patent,[5] and (2) are not covered by Columbia's Covenant. This puts ABC and its affiliates under a reasonable apprehension of suit for their research activities occurring today, and thus Columbia's Covenant is not sufficient to divest this Court of jurisdiction.

IV. COLUMBIA'S CITED FEDERAL CIRCUIT CASES DO NOT SUPPORT THE NARROW COVENANT PROPOSED BY COLUMBIA.

A. The *Super Sack* line of cases does not undermine the need for a more complete covenant in this case.

Columbia seeks to defend its narrowly-drawn covenant by finding solace in the covenants that have been previously endorsed by the Federal Circuit. *See Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059 (Fed. Cir. 1995); *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631 (Fed. Cir. 1991); *Amana Refrigeration, Inc. v. Quadlux, Inc.*, 172 F.3d 852 (Fed. Cir. 1999). But these cases simply did not address the more complex issues that are at the core of the dispute in this case.

Unlike the patents at issue in *Super Sack* and its progeny, the patents in this case include claims to intermediary non-commercial products that may be generated years before a related commercial product is ever brought to market. Claimed "DNA constructs" are used to create the claimed "transformed cells" to create a resulting "proteinaceous material" that can potentially be sold commercially (normally after years of clinical trials). Thus, the issue of taking "concrete steps" to sell a product is much different when talking about biotech products in

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[5] Although Columbia may argue that these research activities are immune from suit under 35 U.S.C. § 271(e)(1), the Federal Circuit has recently held that certain investigatory research into drug candidates is ***not*** covered by the exemption of 271(e)(1). *See Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) (holding that experiments to identify the best drug candidates to submit for future clinical testing and FDA approval were not exempt from infringement allegations under § 271(e)(1)).

the context of the '275 patent claims, since all of the preliminary work with DNA constructs and transformed cells can be alleged to infringe these claims.[6] This is therefore a different situation altogether than that discussed in *Amana*, for example, where the Court was presented with the issue of products "in the pipeline" and found that "an actual controversy cannot be based on fear of litigation over future products." *Amana*, 172 F.3d at 855. Here, Columbia is reserving the ability to allege that the activities and products "in the pipeline" are allegedly infringing the '275 patent claims ***in their own right***, and thus a reasonable apprehension of suit exists based on these research products and activities alone.

This case is also very different than this Court's recent opinion in *SVG Lithography Sys., Inc. v. Ultratech Stepper, Inc.*, --- F.Supp.2d ---, 2004 WL 1948742 (D. Mass., March 6, 2004) (Wolf, J.). In *SVG*, this Court held as follows:

> Although Super Sack could be read to require a plaintiff to waive any future claim of infringement for any product that exists at the time of the motion to dismiss in order to strip the court of subject matter jurisdiction, such a broad requirement is not justified in a case where an existing product is not currently being made, used, offered for sale or sold and there are no concrete plans to recommence activities that could constitute infringement in the future.

Id. at *4. In this case, in contrast, ABC ***is*** currently making HUMIRA®, and Columbia has refused (as *Super Sack* requires) to waive any future claim of infringement ***as to that product***. Thus, the hypothetical situation posited by this Court in *SVG* is actually present here -- ABC has a current product against which Columbia contends it can still assert infringement (either against an affiliate, or against an assignee). Moreover, ABC has research activities making "products"

[6] Of course, "making" an infringing product is an actionable infringement separate and apart from whether the product is ever sold.

that could be accused of infringement ***today*** that are not exempt under Columbia's Covenant. Thus, given the different nature of the patent claims and products at issue, the prior case law is not controlling on Columbia's Covenant and ABC's claims here.

B. The Federal Circuit's decision in *Gen-Probe v. Vysis* does not divest this Court of jurisdiction.

Presumably seeking to excuse the insufficiency of its covenant and its motion to dismiss, Columbia has recently suggested a new argument to divest the Court of jurisdiction -- the Federal Circuit's opinion in *Gen-Probe v. Vysis*, 359 F.3d 1376 (Fed. Cir. 2004). Columbia wrongfully contends that, because Columbia has now reversed course and reinstated the license of ABC (and others of the plaintiffs), there can be no basis for a declaratory judgment lawsuit attacking the validity of the '275 patent. A plain reading of the *Gen-Probe* opinion dispels Columbia's new argument.

In *Gen-Probe*, the Federal Circuit held that a declaratory judgment action could not be maintained by a licensee against its licensor where the licensee had continued to pay royalties to maintain its license. The Federal Circuit noted that "[s]ince the formation of the license, Gen-Probe and Vysis have each fulfilled their obligations without material breach," and "[t]he record discloses no facts that have arisen since the license to give Gen-Probe a reasonable apprehension of a lawsuit." *Id.* at 1381.

The facts of this case are much different. First, ABC has not paid any royalties to Columbia for the '275 patent, or any other patent or patent application deriving from the same patent family. Indeed, Columbia has previously asserted ABC was in breach for not paying royalties. While Columbia has now decided not to terminate ABC's license for failure to pay royalties, the fact that ABC still has its license is not dispositive. The Federal Circuit explained in *Gen-Probe* that "a patent license need not be terminated before a patent licensee may bring a

declaratory judgment action," rejecting "the blanket approach ... that there can never be an apprehension of a federal infringement suit and thus no controversy when a license is still in effect." *Id.* at 1380 (*quoting C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874 (Fed. Cir. 1983)). Thus, Columbia's move to reinstate ABC's license changes nothing with respect to ABC's jurisdictional basis to maintain this suit.

Second, Columbia's letter reinstating ABC's license expressly reserves the right to terminate the license for any grounds other than Abbott's failure to pay royalties. Ex. C. Columbia's original March 9, 2004 letter to ABC stated that Abbott was in breach of its license agreement for, *inter alia*, failure to provide quarterly reports. Ex. H. In Columbia's September 13, 2004 letter withdrawing its notice of termination, it states that "Columbia is not waiving any grounds for termination of the License Agreement, except for the failure to pay royalties based on the '275 patent...." Ex. C. Thus, Columbia is on record stating that it believes it has grounds to terminate ABC, and reserves the right to terminate ABC on those grounds. This is sufficient to form a reasonable apprehension of suit and jurisdiction over ABC's claims.

At bottom, Columbia's new *Gen-Probe* argument is put to rest when considering that the current posture of the case is the same as it was for the first nine months of this litigation. ABC filed suit in July 2003, and Columbia did not send its termination letter until March 2004. Thus, for nine months ABC was a licensee that Columbia had not terminated, yet Columbia did not, and could not, argue that the Court did not have jurisdiction over this lawsuit. The same analysis applies now -- Columbia has chosen to revoke its termination of ABC's license, but ABC still has a reasonable apprehension of termination and the Court still has declaratory judgment jurisdiction to hear this case. Columbia's new *Gen-Probe* argument therefore must be rejected.

V. CONCLUSION

For the foregoing reasons, Plaintiff Abbott Bioresearch Center, Inc. respectfully requests the Court to deny Columbia's Motion to Dismiss.

Date: September 22, 2004

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